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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,528	11/27/2001	Sheng-Ping Zhong	S13.12-0124	8767

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EXAMINER	
SMITH, RUTH S	

ART UNIT	PAPER NUMBER
3737	

DATE MAILED: 08/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/995,528	ZHONG ET AL.	
	Examiner	Art Unit	
	Ruth S Smith	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9,12-25,29-59,63-65,67 and 69-84* is/are pending in the application.

4a) Of the above claim(s) *29-55 and 71-84* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9,12-25,56-59,63-65,67,69 and 70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7,9,14-16,18-25,56-57,59,63-65,67,69 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Young et al. Young et al disclose a medical device such as a catheter having paramagnetic particles incorporated therethrough in order to provide enhanced detectability when viewed by magnetic resonance imaging. The paramagnetic particles are combined with suitable polymeric materials and extruded into a desired shape such

as a flexible tube. The particles may be dispersed uniformly throughout the catheter or may be dispersed in a preselected pattern such as a circumferential band or an axial band extending partially or wholly along the length of the tube. Placement of the particles throughout the catheter would inherently result in some being disposed on the inner lumen surface. In the alternative, the placement of such would have been obvious in view of Young et al disclosing that placement of the particles can be anywhere throughout the catheter. The polymeric material may comprise materials such as Nylon, polyurethane, polyethylene, etc. The paramagnetic materials can comprise a paramagnetic cation incorporated or encapsulated together with a proton-donating fluid in a carrier particle. The paramagnetic ion may be any metal ion displaying paramagnetic properties, typically being an element of atomic numbers 21-29, 42, 44, and 58-70. Exemplary transition metal cations include Gd^{+3}, V^{+4}, V^{+3}, Cu^{+2}, Ni^{+2}, Cr^{+3}, Co^{+3}, Co^{+2}, Cr^{+3}, Fe^{+3}, Fe^{+2}, and the like. The cations will normally be in the form of a salt, including sulfates, chlorides, acetates, nitrates, and the like, as counter ions. With respect to claims 3, 6, 14,19,25, see column 8, lines 16-38. Column 8, lines 40-59 discloses that the paramagnetic particles may be coated or encapsulated with a polymer to form a shell or film. The polymeric coatings disclosed are hydrophilic materials such as cellulose ethers. With respect to claims 21-23, these claims are considered to be product by process claims and the manner in which the product is made fails to affect the patentability of the product.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al in view of Hashimoto et al, or Rhoades et al or Pricone et al. Young et al disclose a medical device such as a catheter having paramagnetic particles incorporated there through in order to provide enhanced detectability when viewed by magnetic resonance imaging. The paramagnetic particles are combined with suitable polymeric materials and extruded into a desired shape such as a flexible tube. The particles may be dispersed uniformly throughout the catheter or may be dispersed in a preselected pattern such as a circumferential band or an axial band extending partially or wholly

along the length of the tube. The polymeric material may comprise materials such as Nylon, polyurethane, polyethylene, etc. The paramagnetic materials can comprise a paramagnetic cation incorporated or encapsulated together with a proton-donating fluid in a carrier particle. The paramagnetic ion may be any metal ion displaying paramagnetic properties, typically being an element of atomic numbers 21-29, 42, 44, and 58-70. Exemplary transition metal cations include Gd^{+3}, V^{+4}, V^{+3}, Cu^{+2}, Ni^{+2}, Cr^{+3}, Co^{+3}, Co^{+2}, Cr^{+3}, Fe^{+3}, Fe^{+2}, and the like. The cations will normally be in the form of a salt, including sulfates, chlorides, acetates, nitrates, and the like, as counter ions. With respect to claims 3, 6, 14,19,25, see column 8, lines 16-38. Column 8, lines 40-59 discloses that the paramagnetic particles may be coated or encapsulated with a polymer to form a shell or film. The polymeric coatings disclosed are hydrophilic materials such as cellulose ethers. With respect to claim 17, the process of cross-linking material to enhance durability is old and well known as shown for example by Hashimoto et al, Rhoades et al and Pricone et al and would have been obvious in that such is a well known expedient in the art.

Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al in view of Weber et al. Young et al disclose a medical device such as a catheter having paramagnetic particles incorporated there through in order to provide enhanced detectability when viewed by magnetic resonance imaging. The paramagnetic particles are combined with suitable polymeric materials and extruded into a desired shape such as a flexible tube. The particles may be dispersed uniformly throughout the catheter or may be dispersed in a preselected pattern such as a circumferential band or an axial band extending partially or wholly along the length of the tube. The polymeric material may comprise materials such as Nylon, polyurethane, polyethylene, etc. The paramagnetic materials can comprise a paramagnetic cation incorporated or encapsulated together with a proton-donating fluid in a carrier particle. The paramagnetic ion may be any metal ion displaying paramagnetic properties, typically being an element of atomic numbers 21-29, 42, 44, and 58-70. Exemplary transition

metal cations include Gd^{+3}, V^{+4}, V^{+3}, Cu^{+2}, Ni^{+2}, Cr^{+3}, Co^{+3}, Co^{+2}, Cr^{+3}, Fe^{+3}, Fe^{+2}, and the like. The cations will normally be in the form of a salt, including sulfates, chlorides, acetates, nitrates, and the like, as counter ions. With respect to claims 3, 6, 14,19,25, see column 8, lines 16-38. Column 8, lines 40-59 discloses that the paramagnetic particles may be coated or encapsulated with a polymer to form a shell or film. The polymeric coatings disclosed are hydrophilic materials such as cellulose ethers. Young et al fails to specifically disclose the use of dysprosium oxide. Weber et al disclose a catheter including paramagnetic materials to enable it to be visualized using MRI. The paramagnetic materials can comprise dysprosium oxide. It would have been obvious to one skilled in the art to have modified Young et al such that the paramagnetic particles are dysprosium oxide. Such a modification merely involves the substitution of one well known type of paramagnetic particle for another.

Claims 12,13,70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al in view of Gillies et al. Young et al disclose a medical device such as a catheter having paramagnetic particles incorporated there through in order to provide enhanced detectability when viewed by magnetic resonance imaging. The paramagnetic particles are combined with suitable polymeric materials and extruded into a desired shape such as a flexible tube. The particles may be dispersed uniformly throughout the catheter or may be dispersed in a preselected pattern such as a circumferential band or an axial band extending partially or wholly along the length of the tube. The polymeric material may comprise materials such as Nylon, polyurethane, polyethylene, etc. The paramagnetic materials can comprise a paramagnetic cation incorporated or encapsulated together with a proton-donating fluid in a carrier particle. The paramagnetic ion may be any metal ion displaying paramagnetic properties, typically being an element of atomic numbers 21-29, 42, 44, and 58-70. Exemplary transition metal cations include Gd^{+3}, V^{+4}, V^{+3}, Cu^{+2}, Ni^{+2}, Cr^{+3}, Co^{+3}, Co^{+2}, Cr^{+3}, Fe^{+3}, Fe^{+2}, and the like. The cations will normally be in the form of a salt, including sulfates, chlorides, acetates, nitrates, and the like, as counter ions. With respect to claims 3, 6, 14,19,25, see column 8, lines 16-38. Column 8, lines 40-59 discloses that the

paramagnetic particles may be coated or encapsulated with a polymer to form a shell or film. The polymeric coatings disclosed are hydrophilic materials such as cellulose ethers. Young et al fails to specifically disclose the use of an antenna in the device. Gillies et al disclose an MR visible catheter having an antenna mounted therein to provide enhanced MR imaging in the area to be diagnosed. It would have been obvious to one skilled in the art to have modified Young et al such that it includes an antenna for detecting MR signals. The advantage of such is to enable enhanced MR imaging in a specific area to be diagnosed in the patient as is well known in the art.

Response to Arguments

Applicant's arguments filed May 27, 2004 have been fully considered but they are not persuasive. Young et al discloses a catheter having paramagnetic particles incorporated therethrough in order to provide enhanced detectability when viewed by magnetic resonance imaging. The paramagnetic particles are combined with suitable polymeric materials and extruded into a desired shape such as a flexible tube. The particles may be dispersed uniformly throughout the catheter or may be dispersed in a preselected pattern such as a circumferential band or an axial band extending partially or wholly along the length of the tube. Placement of the particles throughout the catheter would inherently result in some being disposed on the inner lumen surface. In the alternative, the placement of such would have been obvious in view of Young et al disclosing that placement of the particles can be anywhere throughout the catheter. With respect to claim 17, as previously set forth by the examiner, the use of cross-linking to improve durability is old and well known and the examiner has now provided the evidence of such as requested by applicant.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S Smith whose telephone number is (703) 308-3063. The examiner can normally be reached on M-F 5:30 AM- 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth S Smith
Primary Examiner
Art Unit 3737

RSS